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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,685	09/02/2003	Ken-Shwo Dai	U 014799-1	3481

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EXAMINER	
HUMPHREY, DAVID HAROLD	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,685	DAI, KEN-SHWO	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to an isolated polypeptide of SEQ ID NO: 2, classified in class 530, subclass 300.

II. Claims 1 and 3, drawn to an isolated polypeptide of SEQ ID NO: 4, classified in class 530, subclass 300.

III. Claims 1 and 4, drawn to an isolated polypeptide of SEQ ID NO: 6, classified in class 530, subclass 300.

IV. Claims 5, 6, 9, and 10, drawn to an isolated nucleic acid of SEQ ID NO: 1, classified in class 536, subclass 23.1.

V. Claims 5, 7, 9, and 10, drawn to an isolated nucleic acid of SEQ ID NO: 3, classified in class 536, subclass 23.1.

VI. Claims 5, and 8-10, drawn to an isolated nucleic acid of SEQ ID NO: 5, classified in class 536, subclass 23.1.

VII. Claim 11, drawn to a method of producing a polypeptide of SEQ ID NO: 2 by culturing the host cell containing the nucleic acid of SEQ ID NO: 1, classified in class 435, subclass 69.1.

VIII. Claim 11, drawn to a method of producing a polypeptide of SEQ ID NO: 4 by culturing the host cell containing the nucleic acid of SEQ ID NO: 3, classified in class 435, subclass 70.1.

IX. Claim 11, drawn to a method of producing a polypeptide of SEQ ID NO: 6 by culturing the host cell containing the nucleic acid of SEQ ID NO: 5, classified in class 435, subclass 69.1.

X. Claim 12, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 2, classified in class 424, subclass 130.1.

XI. Claim 12, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 4, classified in class 435, subclass 330.

XII. Claim 12, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 6, classified in class 424, subclass 184.1.

XIII. Claim 13-19, 24, 27, and 30, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene which comprises detecting the nucleic acid of SEQ ID NO: 1, classified in class 435, subclass 6.

XIV. Claim 13-17, 20, 21, 25, 28, and 30, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene which comprises detecting the nucleic acid of SEQ ID NO: 3, classified in class 435, subclass 4.

XV. Claim 13-17, 22, 23, 26, 29, and 30, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene

which comprises detecting the nucleic acid of SEQ ID NO: 5, classified in class 435, subclass 6.

XVI. Claims 13, 31, and 32, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene which comprises detecting the polypeptide of SEQ ID NO: 2, classified in class 435, subclass 7.1.

XVII. Claims 13, 31, and 32, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene which comprises detecting the polypeptide of SEQ ID NO: 4, classified in class 435, subclass 7.23.

XVIII. Claims 13, 31, and 32, drawn to a method of diagnosing a disease associated with the deficiency of a SGII gene which comprises detecting the polypeptide of SEQ ID NO: 6, classified in class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Groups I-VI, and X-XII, are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The polypeptides of Groups I-III and the

nucleic acids of Groups IV-VI have substantially different physical, chemical, structural and functional properties. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo. And while the nucleic acids encode the polypeptides, proteins and nucleic acids have substantially different physical, chemical, structural and functional properties. DNA, deoxyribonucleic acids are unbranched polymers composed of four subunits. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo.

The polypeptide of Groups I-III are related to the antibodies of Groups X-XII by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition or in assays for the identification of agonists or antagonists of the protein.

The polypeptides of Groups I-III are patentably distinct from each other since they constitute different amino acid sequences. The nucleic acids of Group IV-VI are patentably distinct from each other since they differ in their composition and sequence. Groups X-XII are patentably distinct from each other since they recognize patentably distinct sequences and one is not required for the other.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. Groups VII-IX, XIII-XVIII are separate and distinct because they have different method objectives, parameter steps, and utilize distinct reagents. The methods of Groups VII-IX are drawn to methods of producing a polypeptide whereas Groups XIII-XVIII are drawn to methods of diagnosing a disease.

Methods VII-IX are separate and distinct since they require the utilization of patentably distinct nucleic acid sequences of SEQ ID NO's 1, 3, and 5, respectively. Although Groups XIII-XVIII share the same method objective, Groups XIII-XVIII are patentably distinct since they detect separate and distinct amino acid and nucleic acid sequences, each of which utilizes separate reagents not required for the others. For example, Group XIII detects the nucleic acid sequence of SEQ ID NO:1 which is not detected in the methods of any other Groups XIV-XVIII. Therefore, the methods XIII-XVIII are patentably distinct.

Groups IV-VI and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Groups IV-VI can also be used for hybridization assays.

Groups X-XII and XVI-XVIII and are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Groups X-XII can also be used to purify SCII-related protein variants.

Therefore, a search of all Groups I-XVIII would pose an undue search burden on the USPTO's resources.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

February 21, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER